Comments of the Government of Australia on Interim Final Rule; request for comments on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Federal Register Docket No. 02N -0278

The Australian Government submitted in December 2003 comments on the Notice of Interim Final Rule on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Australia is still concerned that the US Bioterrorism Act:

- ?? does not allow for equivalence determinations;
- ?? focuses on prescribing specific measures;
- ?? may lead to more restrictive measures applied to imports than to food and agricultural products produced in the USA for the domestic market;
- ?? appears to be more trade restrictive than necessary;
- ?? may lead to duplication of some measures; and
- ?? does not consider whether the stated objectives are already achieved through the existing controls.

The US FDA re-opened on 1 March 2004 a comment period for 30 days to investigate initial experiences with the new requirements. We wish to provide the following comments:

- ?? Australian exporters have had to carry additional administrative costs resulting from this new requirement.
- ?? Whilst export shipments appear to be currently cleared with no delays caused by the requirement for Prior Notice, this may be because the USFDA is initially taking a flexible approach to the compliance with new requirement. We expect that Australian exporters may start experiencing difficulties when the USFDA enforces fully the new requirement. We therefore believe that the comment period should be re-opened by USFDA when the new requirement for Prior Notice is are fully enforced. This would allow Australia and other countries to make more considered comments on the practical/real impact of the rule.